UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

ONLINE PUBLICATION ONLY

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LUCIA BURGOS,

Plaintiff,

-against-

SATIETY, INC.,

Defendant.

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MEMORANDUM AND ORDER

10-CV-2680 (JG)

A P P E A R A N C E S:

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JOHN GLEESON, United States District Judge:

Plaintiff Lucia Burgos brings suit against defendant Satiety, Inc. ("Satiety"), alleging various forms of products liability, statutory violations, and other state law tort claims. Satiety has moved for summary judgment under Fed. R. Civ. P. 56. The motion is granted, but Burgos is granted leave to file an amended complaint on or before December 17, 2010.

BACKGROUND

On November 19, 2008, Lucia Burgos was a patient at Columbia Presbyterian Hospital undergoing an experimental form of bariatric surgery using a device called the Transoral Gastroplasty Stapling System, to which the parties refer as "TOGA." (Compl. ¶ 60, Def. Mot. at 4.) The TOGA was developed and manufactured by Satiety pursuant to a detailed plan filed with the Food and Drug Administration ("FDA"). Burgos's surgery was part of a series of clinical trials of the TOGA device being conducted around the country pursuant to FDA regulation. (Def. Mot. at 3; *see* Exh. E.) The TOGA was not for general sale, and was used only in the context of the FDA-approved and -regulated trials. (*See* Exh. D.)

Prior to the surgery, Burgos signed a 12-page informed consent form, acknowledging the risks of the procedure and waiving various causes of action against Satiety that might arise from the use of the TOGA device. (Exh. H; *see* Def. Mot. at 4.) During the surgery, Burgos's esophagus was perforated by the TOGA device, allegedly as a result of a malfunction in the device itself rather than any form of negligence by the doctor performing the surgery. (Compl. ¶ 61; Def. Mot. at 4.) Such an injury was explicitly contemplated by the consent form signed by Burgos. (Exh. H at 8 (classifying perforation of the esophagus as one of several "[m]ore serious risks" of the TOGA procedure); *see* Def. Mot. at 4.) After the TOGA device allegedly malfunctioned, the surgeon aborted the TOGA stapling procedure and repaired the perforation of Burgos's esophagus. (*See* Exh. I.) The repair was successful. (*See id.*)

Because of the alleged malfunction, Burgos claims that she has suffered "severe and permanent personal injuries." (Compl. ¶ 60; *see id.* at ¶ 62.) Burgos brought suit against Satiety for her injuries, and Satiety has moved for summary judgment.

DISCUSSION

A. *Summary Judgment*

Summary judgment is appropriate where an examination of the record reveals "no genuine issue of material fact and, based on the undisputed facts, the moving party is entitled to judgment as a matter of law." *D'Amico v. City of N.Y.*, 132 F.3d 145, 149 (2d Cir. 1998); *see* Fed. R. Civ. P. 56(c). All inferences must be drawn and all ambiguities resolved in favor of the nonmoving party. *SCR Joint Venture L.P. v. Warshawsky*, 559 F.3d 133, 137 (2d Cir. 2009). If it appears that a reasonable jury could return a verdict for the nonmoving party, the Court may not grant summary judgment. *Id.* If, however, the moving party demonstrates that there are no genuine issues of material fact, "the nonmoving party must come forth with evidence sufficient to allow a reasonable jury to find in [its] favor." *Roe v. City of Waterbury*, 542 F.3d 31, 36-37 (2d Cir. 2008) (punctuation omitted).

B. *The Federal Regulatory Scheme*

The federal government has been heavily involved in regulating the safety, effectiveness, and development of medical devices since 1938. *Medtronic v. Lohr*, 518 U.S. 470, 475 (1996). Several decades later, in order to deal with a spate of state-law tort claims across the country that followed the failure of several complex medical devices, Congress passed the Medical Device Amendments of 1976, 21 U.S.C. § 360c *et seq.* ("MDA"), which modified the Food, Drug, and Cosmetics Act, 21 U.S.C. § 301 *et seq.* ("FDCA"). *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-16 (2008). The MDA introduced a rigorous pre-market approval process (the "PMA"), which minutely regulates everything from the development, chemical or mechanical composition, and testing of a new device to its labeling, manufacture, and distribution. The PMA is intended to accomplish the MDA's purpose of ensuring the "safety and

effectiveness" of new devices. *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 585 (E.D.N.Y. 2009). No new medical device may be manufactured or marketed until it has gone through the PMA process or its equivalent, and "[a]fter premarket approval, there can be no change in the design, manufacturing or labeling of a medical device that would affect safety or effectiveness of the device" without an extensive review by the FDA. *Id.*

Medical devices in the early testing phase, such as the TOGA, though still governed by the MDA, can be excused from compliance with the PMA via an Investigational Device Exemption ("IDE"). 21 U.S.C. § 360j; *see* 21 C.F.R. § 812 *et seq.*; *Becker v. Optical Radiation Corp.*, 66 F.3d 18 (2d Cir. 1995). The IDE was established "to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose." 21 U.S.C. § 360j(g)(1). An IDE permits clinical trials of a new device sought to be brought to market, providing researchers with a way to test devices whose safety and effectiveness have not yet been proven to the standards otherwise imposed by the PMA. *Id.*; *see United States v. Prigmore*, 243 F.3d 1, 6 (1st Cir. 2001). The requirements of the PMA will be satisfied and the device will be approved for broader use if the IDE investigation "proves the device is sufficiently safe and effective." *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 786 (3d Cir. 1999).

IDE devices remain under the supervision of the FDA during and after the trial process, and the FDA "imposes strict requirements regarding design, manufacture, and safety, [which preempt] states from passing laws, whether court or legislature initiated, affecting such requirements." *Elbert v. Howmedica, Inc.*, 841 F. Supp. 327, 330 (D. Haw. 1993); *see* 21 C.F.R.

§ 812 (imposing over 150 separately numbered regulations on IDE devices). Because IDE devices are subject to a level of FDA oversight and control that is, for the purpose of a preemption analysis, identical to that governing PMA devices, the body of preemption law governing PMA devices applies equally to the IDE device at issue in this case. *See Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090 (6th Cir. 1997) (applying PMA preemption analysis to IDE regulations); *Becker*, 55 F.3d at 21 (applying PMA line of cases to optical device subject to regulations effectively identical to IDE regulations); *Berish v. Richards Medical Co.*, 928 F. Supp. 185, 190 (N.D.N.Y. 1996) (applying *Becker* to IDE devices). Plaintiff does not contend otherwise.

C. *Burgos's State Law Claims of Negligence, Breach of Warranty and Strict Liability are Preempted*

It has long been established that "state law that conflicts with federal law is without effect." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (punctuation omitted). Such a conflict can be created either expressly, via a federal law that specifically preempts a state law or laws, or implicitly, where a federal law "so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it." *Id.* (citations and punctuation omitted); *see Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (Congress's intent to preempt state law can either be "explicitly stated in the statute's language or implicitly contained in its structure and purpose").

One area in which federal law has entirely preempted state law is in the area of the safety and effectiveness of medical devices. The MDA includes an explicit field preemption of every state law requirement "(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this

chapter." 21 U.S.C. § 360k(a). Any state law (whether common law or statute) that would impose upon a device subject to FDA regulation any standard of care, safety, effectiveness, manufacturing, labeling, or any other requirement that goes beyond the responsibilities imposed by the FDA is "different from, or in addition to" the federal requirements, and is thus preempted by the MDA. *Becker*, 66 F.3d at 20 & n.2 (addressing the MDA's preemption of New York common law).

Burgos's complaint apparently alleges three torts under New York law: negligence (Compl. ¶¶ 60-61); breach of warranty (*id.* ¶¶ 65-66);[1] and strict liability (*id.* ¶ 72). Each of these causes of action seeks to impose a burden upon Satiety that is "different from, or in addition to" the requirements established by federal law, and the claims are therefore entirely preempted by federal law. 21 U.S.C. § 360k(a)(1); *see Riegel*, 552 U.S. at 330; *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1303 (D. Colo. 2008) (express warranty, failure to warn, and manufacturing/design defect); *Bausch v. Stryker Corp.*, 2008 WL 5157940, No. 08-cv-4248 (N.D. Ill. Dec. 9, 2008) (strict liability and negligence); *Berish*, 928 F. Supp. at 191-92 (negligent manufacture, breach of express and implied warranty).

D. *Parallel Claims*

Notwithstanding the foregoing, there remains a place for state law claims in this setting. That is because "[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law. 21 U.S.C. § 360k(a)(1). Thus, Section 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case

1 Whether Burgos intends to bring an implied or express warranty claim is unclear -- she alleges that "the defendant . . . represented and warranted that the . . . medical devices . . . were safe and fit for its [sic] intended use and were of merchantable quality" (Compl. ¶ 65), which appears to be a combination of the elements of explicit and implied warranties under the Uniform Commercial Code. *Compare* Unif. Commercial Code §2-313 *with id.* § 2-314. In any event, either claim would be preempted by federal law.

'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (citations omitted); *see also Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 277 (E.D.N.Y. 2009); *In re Medtronic*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009). In order to allege such a claim, a plaintiff must allege a state law violation that parallels a violation of the FDCA -- in this case, presumably an allegation that the design, manufacture, or marketing of the TOGA device deviated in some way from the specifications approved for clinical trials by the FDA. *See Riegel*, 552 U.S. at 330 (noting that strict liability claims are not preempted if "premised on a violation of FDA regulations"); *Williams v. Cyberonics, Inc.*, 2010 WL 2982839, at *2 (3d Cir. July 30, 2010) (denying strict liability because, "[a]lthough it is alleged that the [device] stopped working for [one plaintiff] and malfunctioned for [another], appellants fail to explain how the device deviated from FDA requirements"); *cf. Horn v. Thoratec Corp.*, 376 F.3d 163, 179 (3d Cir. 2004).

Burgos has failed to allege a parallel claim. The complaint does not invoke any federal statute or regulation at all, let alone one that was violated or for which New York law provides a parallel cause of action. To the extent paragraph 69 of the complaint was intended to accomplish such a task, its blunderbuss assertion (*i.e.*, that unspecified "statutes, codes, laws ordinances, rules and regulations" were somehow "violated") is insufficient.

At oral argument, plaintiff's counsel suggested some possible parallel claims that do not appear in the complaint. One is that the defendant disposed of the TOGA device used in plaintiff's procedure, violating federal regulations. Another is a manufacturing defect in the device. Both of these allegations appear to have surfaced after plaintiff's counsel learned that the device had been disposed of.

These parallel claims must be alleged properly. As mentioned, the opaque reference in paragraph 69 to "statutes, codes, laws, ordinances, rules [or] regulations" is no

substitute for a concise allegation of the statute or regulation upon which a parallel claim is based. And unless such a statute or regulation provides for a private right of action, Burgos must also allege the New York cause of action which affords her a right of recovery against Satiety in the event the alleged statutory or regulatory violation is proved.

Although Burgos has not sought leave to amend her complaint, the Court must "freely give leave when justice so requires." Fed. R. Civ. P. 15(a). The Court may, and hereby does, grant leave to amend. *See, e.g., Witkowich v. Holder*, 2010 WL 1328364 (S.D.N.Y. March 31, 2010) (granting leave to amend *sua sponte*); *Hodge v. Unum Group*, 2010 WL 1286257, at *4 (E.D.N.Y. March 30, 2010) (*sua sponte* granting plaintiff leave to move to amend). Because Burgos implied in her papers and explicitly asserted at oral argument a desire to preserve parallel claims, the interests of justice require that she be permitted to amend her complaint to properly state those claims.

CONCLUSION

The defendants' motions are granted in their entirety, and leave to amend is granted. Plaintiff shall file any amended complaint on or before December 17, 2010.

So ordered.

John Gleeson, U.S.D.J.

Dated: November 30, 2010
Brooklyn, New York